MAR 0 5 2007

Exhibit C

K063722

510(k) Summary

Name and address of sponsor of the 510(k) submission:	Techen Safety, Inc. 1901 Powis Ct. West Chicago, IL 60185
Official contact person for all correspondence:	John Allegretti, (address as above) Phone: 800-832-4361, Fax: 630-797-7305 E-mail: cja@techensafety.com
Date Prepared:	November 28, 2006
Device Name:	Sekurit Sharps Collection Containers
Generic name of the device:	Sharps Container
Classification, Product Code and CFR Regulation Number:	Class II, MMK and 21 CFR 880.5570
Classification Panel:	General Hospital
Predicate Device Name and 510(k) Number :	1)B-D@ Guardian One Piece Sharps Collectors, K943139 2) Sage Products, Sharps Disposal Containers with Screw Top Caps, K980490

Device Description:

The Sekurit Sharps Collection Container is a single piece container which is blow molded of High Density Polyethylene plastic and is available in 1 Gallon, 2 Gallon, 3 Gallon and 1.4 quart sizes. Each container is of the same design type and altered only in its height to achieve the needed capacities. The containers are available in translucent red and yellow colors as well as opaque red and yellow colors. Sekurit Sharps Collection Containers have a threaded screw neck and utilize a puncture resistant screw cap molded from Polypropylene. These containers are NOT reusable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Techen Safety, Incorporated
C/O Mr. Neil E. Devine
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

MAR 0 5 2007

Re: K063722
Trade/Device Name: 1GL01-001 -1 Gallon Red Transluscent Sekurit Sharps Collection Container; 1GL01-002-1 Gallon Red Opaque Sekurit Sharps Collection Container; 1GL01-003-1 Gallon Yellow Transluscent Sekurit Sharps Collection Container; 1GL01-004-1 Gallon Yellow Opaque Sekurit Sharps Collection Container; 2GL01-001-2 Gallon Red Transluscent Sekurit Sharps Collection Container; 2GL01-002-2 Gallon Red Opaque Sekurit Sharps Collection Container; 2GL01-003-2 Gallon Yellow Transluscent Sekurit Sharps Collection Container; 2GL01-004-2 Gallon Yellow Opaque Sekurit Sharps Collection Container; 3GL01-001-3 Gallon Red Transluscent Sekurit Sharps Collection Container; 3GL01-002-3 Gallon Red Opaque Sekurit Sharps Collection Container; 3GL01-003-3 Gallon Yellow Transluscent Sekurit Sharps Collection Container; 3GL01-004-3 Gallon Yellow Opaque Sekurit Sharps Collection Container; 1QT01-001-1.4 Quart Red Transluscent Sekurit Sharps Collection Container; 1QT01-002-1.4 Quart Red Opaque Sekurit Sharps Collection Container; 1QT01-003-1.4 Quart Yellow Transluscent Sekurit Sharps Collection Container; 1QT01-004-1.4 Quart Yellow Opaque Sekurit Sharps Collection Container
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: February 16, 2007
Received: February 20, 2007

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general

controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

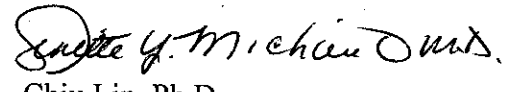
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Not Assigned as of this time

Device Name: Sekurit Sharps Collection Container

Model numbers:

1GL01-001 - 1 Gallon Red Transluscent Sekurit Sharps Collection Container
1GL01-002 - 1 Gallon Red Opaque Sekurit Sharps Collection Container
1GL01-003 - 1 Gallon Yellow Transluscent Sekurit Sharps Collection Container
1GL01-004 - 1 Gallon Yellow Opaque Sekurit Sharps Collection Container
2GL01-001 - 2 Gallon Red Transluscent Sekurit Sharps Collection Container
2GL01-002 - 2 Gallon Red Opaque Sekurit Sharps Collection Container
2GL01-003 - 2 Gallon Yellow Transluscent Sekurit Sharps Collection Container
2GL01-004 - 2 Gallon Yellow Opaque Sekurit Sharps Collection Container
3GL01-001 - 3 Gallon Red Transluscent Sekurit Sharps Collection Container
3GL01-002 - 3 Gallon Red Opaque Sekurit Sharps Collection Container
3GL01-003 - 3 Gallon Yellow Transluscent Sekurit Sharps Collection Container
3GL01-004 - 3 Gallon Yellow Opaque Sekurit Sharps Collection Container
1QT01-001 - 1.4 Quart Red Transluscent Sekurit Sharps Collection Container
1QT01-002 - 1.4 Quart Red Opaque Sekurit Sharps Collection Container
1QT01-003 - 1.4 Quart Yellow Transluscent Sekurit Sharps Collection Container
1QT01-004 - 1.4 Quart Yellow Opaque Sekurit Sharps Collection Container

Indications for Use:

Techen Safety Sharps Disposal Containers with Screw Top Caps are intended for single use disposal of used or contaminated medical sharps, including but not limited to, hypodermic needles, syringes, lancets, and Blood Needles. The containers can be used in a variety of healthcare settings. They are suitable for physicians offices, dental offices, laboratories, home health, patient room, and other generation of medical waste.

Prescription Use _____ **OR** **Over-The Counter Use __X__**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) K063722